510(k) SUMMARY FOR iMRX SYSTEM

1. GENERAL INFORMATION

Establishment:	IMRIS Inc.
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Registration Number:	3003807210
Contact Person:	Mrs. B. Newis Quality Assurance Representative email: bnewis@imris.com Phone: 1-204-480-7070 ext.7043 Fax: 1-204-480-7071
Date of Summary Preparation:	April 15, 2009
Device Name:	iMRX
Trade Name:	IMRISnv / IMRIScardio
Classification Name:	Angiography X-ray system, Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
Classification (CFR section):	21 CFR 892.1600, 21 CFR 892.1000
Class:	Class II
Product Code:	IZI (Angiography x-ray system), LNH (Magnetic Resonance Imaging System)

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2. INTENDED USE OF THE DEVICE

iMRX is an integrated imaging system combining X-ray Angiography and Magnetic Resonance for interventional, diagnostic, and intra-operative imaging.

The iMRX system uses the Artis zee family of dedicated angiography systems for single and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients. Procedures that can be performed with the iMRX system include cardiac angiography, neuro-angiography, general angiography, rotational angiography, operating room angiography and whole body radiographic/fluoroscopic procedures. The iMRX system can also support the acquisition of position triggered imaging for spatial data synthesis.

The iMRX system uses the IMRIS family of Intra-operative MRI systems indicated for use as a magnetic resonance diagnostic device (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and / or spectra, and that display the internal structure and / or function of the head and whole body. Depending on the region of interest, contrast agents may be used. These images and / or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The iMRX system may also be used for imaging during intra-operative and interventional procedures when performed with MR safe devices or MR conditional devices approved for use with the MR scanner.

The iMRX system may also be used for imaging in a multi-room suite.

3. INDICATIONS FOR USE

The iMRX system is indicated for use for the head and whole body.

4. DEVICE DESCRIPTION

The iMRX system is an integrated configuration combining X-ray Angiography and Magnetic Resonance for interventional, diagnostic, and intra-operative imaging. The iMRX system is the integration of a Siemens Artis zee family (biplane or floor mounted single plane) and the IMRISneuro System (Neuro III-SV or Neuro II-SE system). The iMRX system is a solution providing MRI scanning capabilities in the Angiography room while retaining all the functionality of Siemens Artis zee system. The iMRX system includes a traditional MRI unit that has been suspended on an overhead rail system, and is designed to operate inside an RF shielded room to facilitate imaging in multiple rooms. It provides imaging to support intra-operative and interventional capability in the operating room and angio room, while retaining all diagnostic functionality of a standard MRI system in the diagnostic room.

5. SUBSTANTIALLY EQUIVALENT

The iMRX system is substantially equivalent to the following cleared medical devices.

Predicate Device name	510(k) Number	FDA Clearance date
Siemens Artis zee / zeego	K073290	Feb 11, 2008
IMRIS Neuro III-SV Intra-operative MRI System	K083137	Dec 16, 2008
IMRIS Neuro II-SE Intra-operative MRI System	K061916 K071099	Aug 11, 2006 May 22, 2007

6. SAFETY & EFFECTIVENESS

The iMRX has been designed to provide MRI imaging in an intra-operative setting in the same manner as the predicate IMRISneuro (Neuro III-SV/Neuro II–SE) Systems and to provide a complete range of angiography applications in the same manner as the predicate Siemens Arts zee system.

The iMRX system retains all Siemens Artis zee system safety features including visual and audible warnings. To minimize electrical, mechanical and radiation hazards, IMRIS adheres to recognized and established industry practice, and all equipment complies with standard performance testing. Testing has been completed to verify the equivalence of iMRX to the Siemens Artis zee system. This assures that the performance of this device can be considered safe and effective with respect to the currently available Siemens Artis zee system.

The iMRX intra-operative features, including Siemens MRI system, Magnet Mover Assembly, OR Patient Table, Intra-operative Coils and Head Fixation Device are substantially equivalent to the same intra-operative features of the predicate Neuro III-SV and predicate Neuro II-SE. The iMRX does not raise any new safety or effectiveness issues related to the use of a moving MRI system in an intra-operative setting.

The iMRX MRI imaging system's software and hardware are substantially equivalent to the Neuro III-SV (based on the Siemens MAGNETOM Verio 3T MRI) System and the Neuro II-SE (based on the Siemens MAGNETOM Espree MRI) system. The iMRX does not raise any new safety issues related to static magnetic field effects, changing magnetic field effects, RF heating or acoustic noise or effectiveness issues related to specification volume, signal to noise, image uniformity, and geometric distortion, slice profile, thickness and gap, or high contrast spatial resolution. Testing has been completed to verify the equivalence of iMRX to the IMRISneuro (Neuro III-SV/Neuro II-SE) system. This assures that the performance of this device can be considered safe and effective with respect to the currently available IMRISneuro system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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IMRIS, Inc.
% Mr. Thomas M. Tsakeris
President
Devices & Diagnostic Consulting Group, Inc.
16809 Briardale Road
ROCKVILLE MD 20855

Re: K091166
Trade/Device Name: iMRX
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH and IZI
Dated: August 6, 2009
Received: August 10, 2009

Dear Mr. Tsakeris:

This letter corrects our substantially equivalent letter of September 2, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K091166

Device Name: iMRX

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091166